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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,762	09/03/2002	David B Weiner	UPAP0013-100	8614

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EXAMINER	
OUSPENSKI, ILIA I	
ART UNIT	**PAPER NUMBER**
1644	

MAIL DATE	DELIVERY MODE
09/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/980,762	WEINER ET AL.	
	Examiner	Art Unit	
	ILIA OUSPENSKI	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 – 2, 10 – 13, 16 – 22, and 41 – 88* is/are pending in the application.

4a) Of the above claim(s) *16 – 22, 48 – 54, 61 – 67, and 75 – 81* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 – 2, 10 – 13, 41 – 47, 55 – 60, 68 – 74, and 82 – 88* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/2/07;8/14/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed on 07/02/2007 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/02/2007 has been entered.

Claims 1 – 2, 10 – 13, 16 – 22, and 41 – 88 are pending.

Claims 16 – 22, 48 – 54, 61 – 67, and 75 – 81 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Inventions/Species, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in the reply filed on 01/17/2006.

Claims 1 – 2, 10 – 13, 41 – 47, 55 – 60, 68 – 74, and 82 – 88 are under consideration.

2. This Office Action will be in response to Applicant's amendment and arguments, filed on 07/02/2007.

The rejections of record can be found in the previous Office Action, mailed on 01/04/2007.

The objections and rejections of record have been withdrawn in view of Applicant's amendment and arguments, except as set forth herein.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1 – 2, 10 – 13, 41 – 47, 55 – 60, 68 – 74, and 82 – 88 stand rejected under **35 U.S.C. 112, first paragraph**, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. *This is a New Matter rejection.*

Applicant's amendment does not point out the support for the newly added limitations, and the specification as-filed or original claims do not appear to provide adequate written description of the following limitation of claim 1: CD80 protein that is free of "all or part of the CD80 region."

The rejection is maintained for the reasons of record.

Applicant points to a "published PCT application" for support of the newly added limitation.

This response is not seen as pertinent to addressing the rejection of record. Applicant is required to identify support for the newly added limitations in the instant specification as-filed (not a published document), by page number and by line or paragraph number.

Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended claims. The rejection or record is incorporated by reference herein, as if reiterated in full.

5. Claims 1, 10 – 13, 41 – 47, 55 – 60, 68 – 74, and 82 – 88 stand rejected under **35 U.S.C. 112, first paragraph**, because the specification, while being enabling for a nucleic acid molecule that comprises a sequence encoding a CD80 mutant protein comprising "80V that is the variable domain of CD80," "86V that is the variable domain of CD86," etc., does not reasonably provide enablement for a molecule comprising "80V that is the variable domain of CD80 or a fragment thereof," "86V that is the variable domain of CD86 or a fragment thereof," etc.

The rejection is maintained for the reasons of record.

Applicant's arguments have been fully considered but have not been found convincing.

Applicant has amended the claims to remove the adjective "functional" from the recitation of "fragment." Applicant argues that in view of the functional limitations which apply to the whole protein, "there is no need to refer to fragments of the particular regions as being functional or not."

This is not found persuasive, because the instant specification does not provide a sufficient enabling description of how to make fragments of variable domains of CD80 or CD86, etc., such that the fragments result in a functional protein when joined together. Given the unpredictability of the art, as addressed in the previous Office Action, and the lack of working examples, the experimentation left to those skilled in the art required to make such fragments which are useful in the context of the recited protein, is unnecessarily, and improperly, extensive and undue.

Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended claims. The rejection or record is incorporated by reference herein, as if reiterated in full.

6. Claims 13, 47, 60, and 74 stand rejected under **35 U.S.C. 112, first paragraph**, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention. The rejection is maintained for the reasons of record.

The specification does not provide a sufficient enabling description of a "vaccine or attenuated vaccine" comprising a nucleic acid molecule of the invention.

Applicant's arguments have been fully considered but have not been found convincing.

Applicant argues that the reference of Singh et al. does not support the unpredictability of adjuvants, and that the issue of potential toxicity is not a standard for patentability. Applicant further asserts that Sing et al. support the notion that adjuvants are an active field where the discovery of a new adjuvant is not unexpected.

This is not found persuasive, because, although the discovery of a new adjuvant is not unexpected, the development of a "vaccine," i.e. a composition which has a prophylactic or therapeutic effect, is a complex and arduous process, as one of skill in the art is aware and as evidenced by Singh et al. Given that there is insufficient evidence to suggest that the claimed nucleic acids possess prophylactic or therapeutic properties, and the absence of sufficiently detailed guidance or working examples in the

instant specification as-filed as to how to make such compositions, the experimentation left to those skilled in the art, is unnecessarily, and improperly, extensive and undue.

Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended claims. The rejection or record is incorporated by reference herein, as if reiterated in full.

7. Conclusion: no claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ILIA OUSPENSKI, Ph.D.
Patent Examiner
Art Unit 1644

September 6, 2007